

Pellissippi State Technical Community College IRB FAQs

Human Subjects Research and Institutional Review Boards: Questions and Answers

Overview: Since 1991 the National Science Foundation (NSF) and 15 other federal agencies have followed Subpart A of **45 CFR Part 690: Federal Policy for the Protection of Human Subjects**. NSF policy is that all projects involving human subjects must either (1) have approval from an organization's Institutional Review Board (IRB) before issuance of the NSF award or (2) identify the applicable subsection of federal policy exempting the proposal from IRB review. Other federal agencies have similar requirements.

Q: What is an IRB?

A: An Institutional Research Board is an administrative body established to protect the rights and welfare of human subjects in research projects by minimizing risks and ensuring informed and voluntary participation. An IRB is required by federal law to have written procedures that it will follow.

Q: Why does Pellissippi State have to establish an IRB?

A: All institutions that apply for federal funds must establish and register Institutional Review Boards and assure that proposals submitted are compliant with Federal policy.

Q: Why didn't we have an IRB before now?

A: Until recently, it was often assumed incorrectly that if the "human subjects" box was not checked on grant application forms, the proposal was exempt from IRB overview. Because virtually all education projects involve human subjects, NSF now requires program directors to get this information from principal investigators before proceeding with an award recommendation. Many grants are submitted electronically via the Grants.gov Web site. In the future, this site will require grant proposals to indicate the status of human subjects review before grants can be submitted.

Q: What is research?

A: The policy defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (__102(d))

Q: What are human subjects?

A: Human subject means "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (__102(f))

Q: What is meant by "informed and voluntary" participation of subjects?

A: "Informed consent" means ensuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of participation in a research

project so they are able to exercise free power of choice without undo inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

The informed consent of subjects will be obtained by methods that are adequate and appropriate, including full disclosure of all the facts, probabilities, options, and opinions that a reasonable person might be expected to consider before giving his/her consent. A copy of the signed consent form must be given to the person signing the form, and a copy must be kept on file with the investigator or the College, as described in the policies and procedures for the College's IRB. In the case of a minor, the IRB may accept the permission of minor's parent/s or legal guardian, along with the assent of the minor, as required by the federal regulation.

Q: Is my research subject to IRB review?

A: Yes, if it involves human subjects. The federal regulations apply "to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency" that has adopted the regulations for human subjects. (___101(a))

Q: What if the research is not supported by such an agency?

A: Pellissippi State has agreed to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency. Therefore the IRB review process will apply to all research involving human subjects conducted by Pellissippi State faculty, staff or students; conducted with Pellissippi State property; or conducted by others who want to use Pellissippi State employees or students as human subjects.

Q: Can a researcher submit a proposal for human subjects research if his or her institution does not have an IRB?

A: An institution may use an IRB at another institution that is a partner in the proposal until it establishes its own IRB.

Q: Is any research that involves human subjects exempt from regulations requiring a formal IRB review?

A: Yes.

1. Educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation;
2. and research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data.

Q: Does this mean, for example, that I can bypass the formal IRB review process if I survey staff or students who participate voluntarily and who respond anonymously to my research instrument?

A. No, it does not.

1. First, the federal law does not allow you, the researcher, to make the determination of exemption. One or more members of the IRB must review your proposal to decide if it is exempt from the formal IRB review process.
2. Second, there are some exceptions to research using anonymous surveys. For example, if the subjects are children who are under age 18, pregnant women, people with mental or physical disabilities, or prisoners, then the research project will not be exempt.

Q: What requirements do I need to meet if I use a classroom or workshop activity that involves having students or participants question, observe, and interact with one another in ways that may be physically or emotionally stressful?

A: The course instructor or workshop presenter should complete Form A for approval and submit it along with the protocol and any accompanying consent form(s), cover letter(s), and/or questionnaire(s) to obtain guidance of the IRB regarding these activities.

Q: Who is on the IRB?

A: The IRB must have at least five members with varying backgrounds, expertise, and diversity. The chair of the Pellissippi State IRB is the director of the office of Institutional Effectiveness, Research, and Planning. The board must include people with knowledge of College commitments and policies, applicable law, and standards of professional conduct and practice. The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB must include at least one member who is not otherwise affiliated (either directly or through immediate family) with the College.

IRB members are recommended by the director of IR and approved by the president of the College. The roster of Pellissippi State IRB members is reported to the federal regulatory body for human subjects research, the Office of Human Research Protections, which is part of the Department of Health and Human Services. All IRB members are required to undergo formal training, which is available on the Institutional Research website.

Q: How long will the review process take?

- A. The answer depends on the type of IRB action required. Four options are available:
1. Determination of “Exempt” from IRB review for no or minimal risk
 2. Eligible for expedited IRB review
 3. Full IRB review
 4. Continuing IRB review

An investigator does not have the authority to label a project as exempt from IRB review. The director of Institutional Research, serving as IRB chair, reviews Form A applications to determine if a project meets the criteria for exemption. Some projects are not exempt from review, but may be eligible for expedited review (Form B application). If subjects will be exposed to more than minimal risk, the application will be referred to the IRB for review of the full board.

Q: How is minimal risk defined?

A: Minimal risk, as defined in 45 CFR 46, means that the probability and magnitude of harm and discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Q: What research projects qualify for “exempt review”?

A: There are six areas, such as research on educational practices; educational testing; survey and interview procedures; studies of existing, public data or documents; and other research as described in the legislation. There are exceptions to these areas, such as if the human subjects can be identified.

Q: What qualifies as “eligible for expedited IRB review”?

A: This category includes certain clinical studies of drugs and medical devices; collection of blood samples by using specified methods and subjects; collection of biological specimens by specified noninvasive means; collection of data from voice, video, digital, or image recordings made for research purposes only; and other research as detailed in the legislation, including continuing review of research previously approved by the convened IRB that meets certain criteria.

Q: When is review by the full IRB required?

A: Full-board review is required if the project involves more than minimal risk to human subjects or if it does not fall into one of the categories of research eligible for exempt or expedited review. The prospective investigator must complete Form B and submit it for IRB review at least four weeks before the project deadline.

Q: What is “continuing IRB review”?

A: This category of review is to ensure annual review of research previously approved by the IRB. IRB approval of research projects is valid only for one year and must be renewed annually. Projects that have been certified as exempt from IRB review do not need continuing review; however, the investigator may not change the scope or nature of the exempt project without IRB review.

Q: What can the IRB decide?

A: The IRB may take one of four actions in regard to the proposed protocol and consent form:

1. Approve: IRB may approve the project as submitted without any changes noted for a maximum period of 12 months.
2. Approve with Minor Modifications: The IRB may approve a project contingent upon modifications to be completed by the investigator. The director of Institutional Research, serving as IRB chair, will compare the modifications received with the actions requested by the IRB. If the modifications are in compliance with the IRB directives, the director of Institutional Research, serving as IRB chair, will approve the project for a maximum period of 12 months.
3. Table Approval Pending Resubmission: – If the IRB deems that the proposal and/or informed consent as submitted require major revisions, the IRB will

require the investigator to resubmit the application and attachments with all of the changes required. Approval of the revised proposal is contingent on the results of discussion and vote by the reconvened IRB.

4. Disapprove: The IRB may disapprove a research project if it has determined that the human subjects are at a greater risk than the benefits to be accrued. The director of Institutional Research, serving as IRB chair, will notify the investigator in writing. Notification will include all of the reasons and rationale behind the disapproval. The investigator may revise and resubmit the project to address IRB concerns, such as reducing risks to subjects.

Q: Is there an appeal process?

A. Yes. The investigator can appeal the IRB's decision by sending a written request documenting the basis of the appeal to the director of Institutional Research, serving as IRB chair. Only one appeal may be rendered. Final disapproval of the IRB cannot be overridden by any College officials, but College officials may review and disapprove research approved by an IRB.

Q. Can investigators contact potential subjects prior to IRB review?

A. No. Investigators may not solicit subject participation or begin data collection until you have obtained approval by the Pellissippi State IRB.